OCT 2 2 2003

K032686

510(k) SUMMARY

SUBMITTER NAME: Ascension Orthopedics, Inc.
8200 Cameron Road, C–140
Austin, TX 78754-3832

510(k) CONTACT: Peter Strzepa
Phone: (512) 836-5001

TRADE NAME: Ascension® Modular Radial Head

COMMON NAME: radial head prosthesis

CLASSIFICATION: 21 CFR §888.3170

PRODUCT CODE: 87 KWI

PANEL: Orthopedic and Rehabilitation Devices

PREDICATE DEVICE:
Avanta Orthopaedics, Inc., Radial Head Implant (K982288)
Wright Medical Technology, Inc., Modular Radial Head (K991915)

DEVICE DESCRIPTION:
The Ascension® Modular Radial Head is an anatomically designed, single-use, modular prosthesis designed for replacement of the proximal end of the radius. It is made from ASTM F1537 cobalt chromium alloy. Head components available in six sizes and stem components available in four sizes are interchangeable and achieve assembly by means of a taper connection.

INTENDED USE:
The Ascension® Modular Radial Head is intended for:

- Replacement of the radial head for degenerative or post-traumatic disabilities presenting pain, crepitation, and decreased motion at the radio-humeral and/or proximal radio-ulnar joint with:
  - joint destruction or subluxation visible on x-ray
  - resistance to conservative treatment
- Primary replacement after fracture of the radial head
- Symptomatic sequelae after radial head resection
- Revision following failed radial head arthroplasty

BASIS OF SUBSTANTIAL EQUIVALENCE:
A comparison of materials and design features, as well as performance tests and analyses, demonstrate that the Ascension® Modular Radial Head is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 2 2003

Mr. Peter Strzepa
Vice President, Science and Technology
Ascension Orthopedics, Inc.
8200 Cameron Road, C-140
Austin, TX 78754-3832

Re: K032686
Trade/Device Name: Ascension® Modular Radial Head
Regulation Number: 21 CFR 888.3170
Regulation Name: Elbow joint radial (hemi-elbow) polymer prosthesis
Regulatory Class: II
Product Code: KWI
Dated: August 29, 2003
Received: August 29, 2003

Dear Mr. Strzepa:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use

510(K) Number: K032686 K032686

Device Name: Ascension® Modular Radial Head

Indications for Use:

The Ascension® Modular Radial Head is intended for:

- Replacement of the radial head for degenerative or post-traumatic disabilities presenting pain, crepitation, and decreased motion at the radio-humeral and/or proximal radio-ulnar joint with:
  - joint destruction or subluxation visible on x-ray
  - resistance to conservative treatment
- Primary replacement after fracture of the radial head
- Symptomatic sequelae after radial head resection
- Revision following failed radial head arthroplasty

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

for Mark N Milhous

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K032686

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